

II. 510(k) SUMMARY

Submitted by: UNIDUS Corporation
Seokyung Building 51, Bangi-Dong
Songpa-Ku
Seoul, Republic of Korea *NOV 15 2007*

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Date Prepared: September 27, 2007

Proprietary Name: UNIDUS or Private Label

Common Name: Male Latex Condom

Classification Name: Male Latex Condom

Predicate Device: Carter-Wallace Version One Trojan Extra Large Latex Condom
With silicone lubricant 510(k) number K001212

Description of Device:

This condom is made of a natural latex sheath, which completely covers the erect penis with a closely fitted membrane. This condom is straight-walled with a reservoir tip; nominal length 205mm, nominal flat width 57mm, and nominal thickness 0.06mm. It is lubricated with silicone and cornstarch is used as a dressing material. This condom is designed to conform to established national and international voluntary standards including ASTM D3492 and ISO 4074.

Intended Use of the Device:

This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for

prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted diseases, including HIV.

Technological Characteristics:

This condom has the same technological characteristics as the predicate condom identified above. The design is in conformance with ASTM Latex Condom Standard D3492 and the condom is made from the same natural rubber latex compound as listed in UNIDUS 510(k) number K023059 along with using the same production equipment. The Magnum Latex Condom is designed with a longer length of 205mm and wider flat width of 57mm for the man who needs a larger size condom.

The UNIDUS Magnum Latex Condom is intended for men who feel that current regular size condoms are too small.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 15 2007

Mr. Claude L. Wright
Consultant to UNIDUS Corporation
507 Shallow Creek Road
TUSCALOOSA ALABAMA 35406

Re: K072747

Trade Name: UNIDUS or Private Label
Regulation Number: 21 CFR §884.5300
Regulation Name: condom
Regulatory Class: II
Product Code: HIS
Dated: September 27, 2007
Received: September 27, 2007

Dear Mr. Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

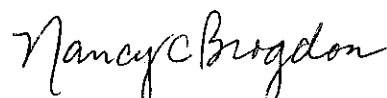
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VII. INDICATIONS FOR USE STATEMENT

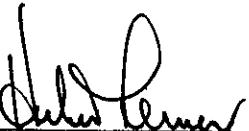
510(k) Number Not Known K072747

Device Name Male Natural Rubber Latex Condom

Indications for Use: The UNIDUS condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use ✓
(Per 21 CFR 801.109)


(Division Sign-Off)

Division of Reproductive, Abdominal, and
Radiological Devices

510(k) Number K072747